



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 2, 2014

Biomet Sports Medicine
Dr. Jared Cooper
Regulatory Specialist
56 East Bell Drive
Warsaw, Indiana 46582

Re: K140908

Trade/Device Name: JuggerKnot™ Mini Soft Anchors
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: September 2, 2014
Received: September 3, 2014

Dear Dr. Cooper

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Susan Runne DDS, MA". The "FDA" logo is faintly visible in the background behind the signature.

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and
Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140908

Page 1 of 1

Device Name: JuggerKnot™ Mini Soft Anchors

Indications For Use:

The JuggerKnot™ Mini Soft Anchors are intended to be used for soft tissue to bone fixation with indications for use in:

Maxillofacial

For the repair, repositioning or reattachment of soft tissues, ligament and tendons to the mandible for surgical stabilization of the TMJ articular disc.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



510(k) Summary

Preparation Date: 2 September, 2014

Applicant/Sponsor: Biomet Sports Medicine

Contact Person: Jared Cooper, Regulatory Specialist – Sports Medicine

Proprietary Name: JuggerKnot™ Mini Soft Anchors

Common Name: Soft Tissue Fixation Device

Classification Name: Intraosseous fixation screw or wire
(21 CFR 872.4880) DZL.

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K992623	Mitek® Mini Anchor
K992487	Mitek Mini QUICKANCHOR Plus
K080352	Mitek Mini QUICKANCHOR Plus and Microfix QUICKANCHOR Plus
K110879	Biomet Sports Medicine JuggerKnot™ Mini Soft Anchors

Device Description:

The JuggerKnot™ Mini Soft Anchors consist of a coreless sleeve structure and suture. The anchors are intended for use in soft tissue fixation by bunching against bone when deployed.

Intended Use / Indications for Use:

The JuggerKnot™ Mini Soft Anchors are intended to be used for soft tissue to bone fixation with indications for use in:

Maxillofacial

For the repair, repositioning or reattachment of soft tissues, ligament and tendons to the mandible for surgical stabilization of the TMJ articular disc.

Summary of Technologies:

The JuggerKnot™ Mini Soft Anchors are similar or identical to the predicate devices in the following technological characteristics:

Anchor Material: The JuggerKnot™ Mini Soft Anchors are made from Polyester and Polyethylene. These are the same materials as the predicate JuggerKnot™ Mini Soft Anchors (K110879).

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Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Suture Material: The suture material for the JuggerKnot™ Mini Soft Anchors is a combination of Polyester, Polyethylene, Polypropylene and/or Nylon. These are the same suture materials as the predicate JuggerKnot™ Mini Soft Anchors (K110879). The predicate Mitek Anchors (K992623 and K080352) include a polyester suture material that is similar. The suture needles used in all of the anchors that include a suture needle are made of surgical stainless steel.

Design: The JuggerKnot™ Mini Soft Anchors consist of a coreless sleeve designed to be inserted into a pre-drilled hole and anchor into the bone. This is the same design as the predicate JuggerKnot™ Mini Soft Anchors (K110879). The predicate Mitek Anchors consist of a solid anchor designed to be inserted into a pre-drilled hole and anchor into the bone.

Fixation Mode: The JuggerKnot™ Mini Soft Anchors are held in place by compression of the sleeve within the hole. This is identical to the fixation mode of the predicate JuggerKnot™ Mini Soft Anchors (K110879).

Non-Clinical Testing:

Non-clinical laboratory testing was performed to verify the fixation strength of the JuggerKnot™ Mini Soft Anchors in mechanical pullout testing as compared to the predicate devices. Comparison testing was conducted to evaluate the average pullout strength of the JuggerKnot™ Mini Soft Anchors and the Mitek Mini QUICKANCHOR® Plus with the acceptance criteria being that the average pullout strength would be statistically equal to or greater than that of the Mitek anchors. The test results indicate that the Biomet Sports Medicine JuggerKnot™ Mini Soft Anchors provide at least equivalent fixation strength to the predicate devices. The acceptance criteria were met, demonstrating that the JuggerKnot™ Mini Soft Anchors are substantially equivalent in pullout strength to the predicate devices.

Clinical Testing:

None provided as a basis for substantial equivalence.

Conclusions:

The similarities in material, design and fixation mode between the subject JuggerKnot™ Mini Soft Anchors and the predicate devices, in conjunction with the comparison testing demonstrate that the JuggerKnot™ Mini Soft Anchors are as safe, as effective, and perform as well as the predicate devices.

All trademarks are the property of Biomet, Inc., except for Mitek® and QUICKANCHOR® which are the property of DePuy Mitek / Mitek Products.